4.0 ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS), HUMAN PITUITARY DERIVED GROWTH HORMONE (HPDGH), AND REPORTING OF POTENTIAL RECIPIENT DISEASES OR MEDICAL CONDITIONS, INCLUDING MALIGNANCIES, OF DONOR ORIGIN

4.1 SCREENING POTENTIAL ORGAN DONORS FOR HIV. All potential donors are to be tested by use of a screening test licensed by the U.S. Food and Drug Administration (FDA) for Human Immune Deficiency Virus (HIV). If the potential donor's pre-transfusion test for HIV is negative and blood for subsequent transfusions has been tested and found to be negative for HIV, retesting the potential donor for HIV is not necessary. If no pre-transfusion sample of the potential donor's blood is available, the Host OPO (as defined in Policy 2.1) must provide, to the recipient transplant center the screening test results and a complete history of all transfusions received by the donor during the ten (10) day period immediately prior to removal of the organ. Organs from donors with a positive screening test are not suitable for transplantation unless subsequent confirmation testing indicates that the original tests' results were falsely positive for HIV. If additional tests related to HIV are performed, the results of all tests must be communicated immediately to the Organ Center and all institutions receiving organs from the donor. Exceptions for cases in which the testing cannot be completed prior to transplant are provided in paragraph 4.1.3 below.

4.1.1 Communication of Donor History. The Host OPO will obtain a history on each potential donor in an attempt to determine whether the potential donor is in a "high risk" group, as defined by the Centers for Disease Control and Prevention (CDC). If the donor meets the criteria set forth in CDC Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs (CDC Guidelines),[1] the Host OPO must communicate this information regarding donor history to all institutions receiving organs from the donor.

If the transplant center receives information from the Host OPO that the donor meets any of the criteria, the transplant center must inform the potential recipient prior to implantation. The transplant center shall maintain documentation of the potential recipient's informed consent to receive an organ from the donor who meets any of the criteria. In the event that the potential recipient is not able to provide informed consent, the legal next of kin, designated healthcare representative, or appropriate surrogate may provide consent on this matter.

4.1.2 Organ Sharing. Members shall not knowingly participate in the transplantation or sharing of organs from donors who are confirmed HIV positive by an FDA licensed screening test unless subsequent confirmation testing unequivocally indicates that the original test's results were falsely positive for HIV.

4.1.3 Exceptions. Exceptions to the guidelines set forth above may be made in cases involving non-renal organs, when, in the medical judgment of the staff of the Host OPO and recipient institution, an extreme medical emergency warrants the transplantation of an organ, the donor of which has not been tested for HIV. The transplant surgeon is obligated to obtain informed consent from the recipient or next of kin in such cases.

4.1.4 Donor Consent Forms. Member institutions are encouraged to include in each donor consent form a notice that all potential donors will be screened for medical

[1] Rogers MF, Simonds RJ, Lawton KE, et al. Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs. CDC MMWR Recommendations and Reports. 1994;May 20/ 43(RR-8):1-17. http://www.cdc.gov/mmwr/preview/mmwrhtml/00031670.htm

acceptability for organ donation and that results of such tests may be the basis for not using the organ in transplantation.

4.2 SCREENING POTENTIAL TRANSPLANT RECIPIENTS FOR HIV. Testing for HIV shall be a condition of candidacy for organ transplantation, except in cases where such testing would violate applicable state or federal laws or regulations. Candidates whose test results are confirmed positive should undergo appropriate counseling.

4.2.1 HIV Positive Transplant Candidates. A potential candidate for organ transplantation whose test for HIV is positive but who is in an asymptomatic state should not necessarily be excluded from candidacy for organ transplantation, but should be advised that he or she may be at increased risk of morbidity and mortality because of immunosuppressive therapy.

4.2.2 Informing Personnel. Health care personnel caring for donors, potential donors, candidates, potential candidates and recipients who test positive for HIV should be so informed.

4.2.3 Candidate and Recipient Treatment. Administering treatment to candidates and recipients who test positive for the HIV should not be optional or discretionary for health care personnel.

4.3 DISCLOSURE OF INFORMATION ABOUT HIV STATUS. Member institutions are urged to comply with state and federal statutes and regulations applicable to the disclosure of personalized data on actual or potential organ donors, candidates or recipients.

4.4 GENERAL RECOMMENDATIONS. All member institutions are requested to adopt an overall health care policy addressing special HIV-related problems with regard to transplant candidates and recipients. It is recommended that each institution's HIV-related health care policies incorporate the specific Policies 4.1, 4.2, and 4.3 set forth above. It is also recommended that member institutions make their policies available upon request to the press and the public.

4.5 HUMAN PITUITARY DERIVED GROWTH HORMONE. People who have received Human Pituitary Derived Growth Hormone (HPDGH) from human tissue (not recombinant) shall be evaluated as organ donors with potential organs used at the discretion of the accepting transplant center and with informed consent from the potential recipient. The transplant surgeon is obligated to obtain informed consent from the recipient or next of kin in such cases. The use of recombinant HPDGH carries no additional risk of transmissible disease.

4.6 SCREENING POTENTIAL ORGAN DONORS FOR TRANSMISSION OF DISEASES OR MEDICAL CONDITIONS, INCLUDING MALIGNANCIES. All potential donors are to be screened for transmissible diseases or medical conditions, including malignancies, through the collection of medical/social history information. Donor testing for the purpose of organ allocation **must** use a FDA licensed, approved or cleared test if commercially available.

Medical conditions that should be screened for by history include the presence of malignancies, treated and untreated, or any other known condition that may be transmitted by the donor organ that may reasonably impact the candidate or recipient. In addition, donors shall be tested for recognized transmissible diseases, as defined in policy 2.2.8.1, using FDA-licensed, approved, or cleared serological screening tests capable of determining whether the donor is or has been infected with these specific diseases. In the event that such screening tests are not commercially

available prior to transplant, then a FDA approved diagnostic test is permissible to assess the donor.

If additional testing is performed, the results of these tests must be communicated immediately to all recipient institutions. The OPO is responsible for timely follow-up of donor screening tests. Documentation of any suspected or confirmed transmissible disease or medical condition identified prior to or following procurement must be communicated by the Host OPO to all potential recipient centers and the OPTN according to Policy 4.7.

NOTE: The amendments toPolicy4.6 Screening Potential Organ Donors For Transmission Of Diseases Or Medical Conditions, Including Malignancies shall be effective pending distribution of appropriate notice. (Approved at the March 2009 Board of Directors Meeting)

4.6.1 **Donor History.** The Host OPO will obtain a history on each potential donor in an attempt to determine whether the potential donor is in a "high risk" group, as defined by the Centers for Disease Control. The Host OPO must communicate the donor history to all recipient institutions.

4.6.2 **Reporting.** Known conditions that may be transmitted by the donor organ must be communicated to the transplant centers: These may include, but are not limited to, the following:

- Unknown infection of central nervous system (encephalitis, meningitis)
- Suspected Encephalitis
- Hepatitis C
- Herpes simplex encephalitis or other encephalitis
- History of JC virus infection (causes progressive multifocal leukoencephalopathy)
- West Nile virus infection
- Cryptococcal infection of any site
- Rabies
- Creutzfeldt-Jacob disease
- Other fungal or viral encephalitis
- Bacterial meningitis
- Infection with HIV (serologic or molecular)
- Active viremia: herpes, acute EBV (mononucleosis)
- Serologic (with molecular confirmation) evidence of HTLV-I/II
- Active hepatitis A or B
- Infection by: Trypanosoma cruzi, Leishmania, Strongyloides, Toxoplasmosis
- Active Tuberculosis
- SARS
- Pneumonia
- Bacterial or fungal sepsis (e.g. candidemia)
- Syphilis
- Multi-system organ failure due to overwhelming sepsis, such as gangrenous bowel
- Malignancies-other active malignant neoplasms,
- Melanoma, Merkel cell, including Kaposi’s
- Hodgkins’ disease and non-Hodgkin’s lymphoma
- Multiple myeloma
- Leukemia
- Aplastic anemia agranulocytosis
- Miscellaneous carcinomas

- Any new conditions identified by the CDC as being a potentially communicable disease

4.6.3 **Exceptions.** Organs from donors with a positive screening test or confirmed medical conditions that may be transmittable, with the exception of HIV, may be transplanted at the discretion of the transplanting program with the informed consent of the recipient.

4.6.4 **Donor Consent Forms.** Member institutions are encouraged to include in each donor consent form a notice that all potential donors will be screened for medical acceptability for organ donation and that results of such tests may be the basis for not using the organ in transplantation.

4.7 POST-TRANSPLANT REPORTING OF POTENTIAL TRANSMISSION OF DISEASE OR MEDICAL CONDITIONS, INCLUDING MALIGNANCIES. When a transplant program is informed that an organ recipient at that program is confirmed positive for or has died from a transmissible disease or medical condition for which there is substantial concern that it could be from donor origin, the transplant program must notify by phone and provide available documentation, as soon as possible and not to exceed one complete working day, to the procuring OPO. The overall intent is to transfer the knowledge/concern from one transplant center to all other transplant centers who have accepted organs from the same donor as quickly as possible. The transplant center originating the concern of transmissibility should not wait for all medical documentation that will eventually be available, but communicate that center's concerns through the OPO and OPTN to all other centers involved with that same donor as soon as possible so the other centers could use their medical judgment as to which, if any, investigations or actions need to be performed on their recipients.

The procuring OPO shall be responsible for:

i. communication of the test results and diagnosis as soon as practicable to any transplant center and tissue bank that received an organ or tissue from the donor who is the subject of the investigation;
ii. management of the investigation to determine whether the organ donor was diagnosed with a potentially transmissible disease or condition;
iii. notification of the event to the OPTN as soon as possible; and
iv. submission of a final written report to the OPTN within 45 days, which specifies the organizations and individuals who were notified, when the notifications occurred, and results of the investigation including test results of the organ recipients who are the subjects of the investigation.

The OPTN shall assist the procuring OPO in identifying all organ transplant programs and recipients who received an organ from the donor who is the subject of the investigation. The OPTN will monitor the notification process to verify that the procuring OPO and all recipient organ transplant programs have been notified of the disease or medical condition and will request that any additional diagnostic test results be submitted to the procuring OPO with a copy to the OPTN. The OPTN contractor will forward a copy of the OPO's final report to the recipient transplant centers and the Division of Organ Transplantation of the Health Resources and Services Administration. Note: The identities of the donor and any organ recipient who are the subjects of the investigation shall remain confidential and all correspondence will refer to the donor and recipients by their donor identification number and recipient social security numbers. Under no circumstances should a transplant program or OPO disclose this information in a manner that is contrary to applicable law.